DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0228]

Determination of Regulatory Review Period for Purposes of Patent Extension; Neuro Cybernetic Prosthesis (NCP®) System; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending a previous determination regarding the regulatory review period for the Neuro Cybernetic Prosthesis (NCP®) System that appeared in the **Federal Register** of November 10, 1998 (63 FR 63066). FDA is amending the notice because the agency agrees with the information provided in a request from the applicant for revision of the regulatory review period (Request) (Docket No. 98E–022 8/PRC 1, dated and received on January 8, 1999).

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: In its original application for patent term extension, the applicant claimed December 16, 1991, as the date the premarket approval application (PMA) for the Neuro Cybernetic Prosthesis (NCP®) System (PMA 910070) was initially submitted. FDA first determined that the PMA was initially submitted on January 27, 1997, because FDA records indicated that the PMA submitted on December 16, 1991, had not been filed, but an amended PMA, renumbered as PMA 970003, was the PMA for the approved product.

The applicant later claimed in its request that FDA's determination of the regulatory review period failed to take into account an approved amendment to the applicant's originally submitted PMA. Therefore, the applicant requested that the agency correct the date the PMA was initially submitted to June 1, 1993, the date the approved amendment to the PMA was received by FDA.

FDA reviewed its records and confirmed that the amended PMA, received on June 1, 1993, was filed by the agency based on a threshold determination that the amended PMA was sufficiently complete to permit a substantive review. FDA later determined that additional studies were required and issued a major deficiency letter dated September 30, 1994, requesting that additional clinical studies be performed. The applicant submitted a second amendment to the PMA, which the agency received on January 27, 1997. FDA reviewed the amendment and determined that the second amendment sufficiently responded to the September 30, 1994, deficiency letter, and filed the newly amended PMA on the date of the receipt of the completed PMA, January 27, 1997. For administrative reasons, the second amendment to the PMA was considered a resubmission of the PMA, and it was assigned a new PMA number, P970003, which is the PMA number of the approved PMA for the product.

In the past, FDA has determined that the start of the approval phase began with the submission of the first filed PMA for an approved product, even if the original filed PMA was later withdrawn and filed under a new number. For this reason, FDA now accepts the date of June 1, 1993, submitted by the applicant in its request, as the date the first PMA was filed for the product and the date that the PMA was initially submitted.

Therefore, the applicable regulatory review period for the Neuro Cybernetic Prosthesis (NCP®) System is 3,237 days. Of this time, 1,730 days occurred during the testing phase of the regulatory review period, while 1,507 days occurred during the approval phase.

These periods of time were derived from the following dates, summarized from the November 10, 1998, notice and modified by this technical amendment:

1. *The date a clinical investigation involving this device was begun*: September 6, 1988.

2. *The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e)*: June 1, 1993.

3. *The date the application was approved*: July 16, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,761 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before [*insert date 60 days after date of publication in the* **Federal Register**], submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before [*insert date 180 days after date of publication in the* **Federal Register**], for a determination on whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit one copy. Comments

are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 6, 2000

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

BILLING CODE 4160–01–F